

REMARKS

Applicant respectfully requests reconsideration of the above-identified patent application in view of the amendment above and the remarks below.

No claims have been canceled or added herein. Claims 1 and 24 have been amended herein. Therefore, claims 1-24 are pending and are under active consideration.

Claims 1-24 stand rejected under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement." In support of the rejection, the Patent Office states the following:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Here, the new limitation to claim 1, "nonspecifically with regard to methylation of said genomic DNA sample" is apparently new matter. There was no citation of any location in the specification which supported this limitation. A careful review by the examiner of the specification failed to identify any support for this new negative limitation. In particular, while page 10 discusses amplification, as do pages 11 and 12, there is no discussion whatsoever to support a negative limitation that the genomic DNA sample is amplified "nonspecifically with regard to methylation."

As noted by MPEP 2173.05(l),

"Any negative limitation or exclusionary proviso must have basis in the original disclosure. See Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983) aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis

in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.”

Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Although disagreeing with the propriety of the rejection, Applicant has deleted the language in question from claim 1. Therefore, the rejection is moot and should be withdrawn.

On page 2, paragraph 1, of the outstanding Office Action, the Patent Office states that, “[w]hile the 103(a) rejection over [claims 1-23] is currently withdrawn in view of the amendment, the rejection would be reapplied and the action made final, if the new matter is removed from the claims.” For at least the reasons below, Applicant respectfully submits that such a reinstatement of the previously applied 103(a) rejection would be in error since the previously applied references, taken individually or in combination, do not teach or suggest claim 1, from which claims 2-24 depend.

In particular, the previously applied references do not teach or suggest, among other things, the claimed step of “contacting a set of probes of different nucleobase sequences, each of which contains the dinucleotide sequence 5'-CpG-3' at least once, to the immobilized DNA samples for hybridization to distinguish methylated and nonmethylated cytosines in said genomic DNA sample.” As noted previously, Herman et al. relates to a technique referred to therein as “methylation specific PCR” or MSP. MSP involves “contacting a nucleic acid-containing specimen with an agent that modifies unmethylated cytosine, amplifying the CpG-containing nucleic acid in the specimen by means of CpG-specific oligonucleotide primers, wherein the oligonucleotide primers distinguish between modified methylated and non-methylated nucleic acid and detecting the methylated nucleic

acid” (col. 5, line 62 through col. 6, line 1, of Herman et al.). In other words, MSP “uses the PCR reaction itself to distinguish between modified methylated and unmethylated DNA” (col. 4, line 67 through col. 5, line 1 of Herman et al.) as the “MSP primers themselves are specifically designed to recognize CpG sites to take advantage of the differences in methylation to amplify specific products” (col. 5, lines 6-8, of Herman et al.). Because Herman et al. is predicated upon the preferential or specific amplification of methylated, as opposed to unmethylated, nucleic acids (or vice versa), Herman et al. does not use probes containing the dinucleotide sequence 5'-CpG-3' at least once to **distinguish methylated and nonmethylated cytosines** in said genomic DNA sample. There is because, following MSP, there are no methylated and nonmethylated cytosines **to be distinguished**.

Applicant’s other previously presented arguments relating to deficiencies of the previously applied references are incorporated herein by reference.

Claim 24 stands rejected under 35 U.S.C. 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In support of the rejection, the Patent Office states the following:

It is vague and indefinite what is meant by the phrase “are immobilized on the latter.” On the “latter” what? It is entirely unclear to which thing the term “latter” is referring, whether it is the “sample holder”, the “mass spectrometer”, the “kit” or something else.

It is vague and indefinite what is meant by the entire phrase “containing a sample holder for a mass spectrometer which is modified in such a way that randomly selected portions of a genome are immobilized on the latter, and/or probe libraries”. Is this claim referring to alternatives of a kit with a probe library or a kit with a sample holder. The claim states “and/or probe libraries”, but it is unclear to what element the “or” is referring. Further, it is entirely unclear whether the sample holder must have DNA immobilized on it, or whether the sample holder simply must be capable of having

DNA immobilized to it. Given these significant ambiguities, the Koster reference is applied below as a 102 rejection, since Koster meets, within limits of intelligibility, the structural limitations of this claim.

Applicant respectfully traverses the subject rejection. Claim 24 has been amended herein.

As amended, claim 24 is respectfully submitted to be definite.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claim 24 stands rejected under 35 U.S.C. 102(b) "as being anticipated by Koster et al." In support of the rejection, the Patent Office states the following:

Koster teaches kits (see column 20, lines 15-49) which contain:

Sample holders such as solid supports for mass spectrometer measurement (see column 20, line 18-24, for example)

Nucleic acids (see column 20, lines 15-49),

Optional buffers (see column 20, lines 38-41, which meets the other chemicals, solvents and adjuvants alternative element).

Koster expressly teaches supports with nucleic acids bound to them (see column 22, example 2).

It is noted that the instructions are given no patentable weight.

Applicant respectfully traverses the foregoing rejection. Claim 24, as amended herein, is neither anticipated by nor rendered obvious over Köster for at least the reason that Köster fails to teach or to suggest a kit comprising, among other things, (i) a sample holder for a mass spectrometer, wherein the sample holder is modified in such a way that randomly selected portions of a genome may be immobilized on the sample holder, and (ii) probe libraries with which the DNA immobilized on the sample holder is analyzed by mass spectrometer.

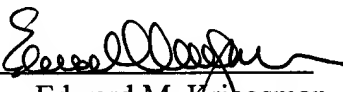
Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

In conclusion, it is respectfully submitted that the present application is in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

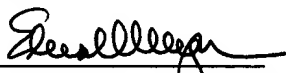
Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 24, 2004


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